National Coverage Determinations Relevant to Therapy Services

According to the Code of Federal Regulations [42CFR400.202], a "national coverage determination [NCD] is a national policy determination regarding the coverage status of a particular service that CMS [the Center for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration (HCFA)] makes under §1862(a)(1) of the Social Security Act (the Act), and publishes as a Federal Register notice or CMS ruling. (The term does not include coverage changes mandated by statute)." These NCDs are usually published in HCFA Pub. 6, the Coverage Issues Manual. Many services and supplies related to the delivery of physical therapy, occupational therapy, and speech-language pathology services are addressed in the NCDs. The following text is a compilation of those current NCDs that the DynCorp Therapy Review Program has identified as most relevant to providers of rehabilitation therapy services under Medicare. Links have been included within the document, as well as to the source documents to aid in further research by the user. Additionally, the user may refer to the CMS '*Medicare Coverage Policy – Home page'* at: http://www.cms.hhs.gov/coverage/default.htm. Here, the status of pending national coverage decisions is presented.

HCFA Pub. 6 Coverage Issues Manual

The Coverage Issues Manual states whether specific medical items, services, treatment procedures or technologies can be reimbursed under Medicare. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on §1862(a)(1) of the Social Security Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the sole authority for denial. Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services that they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in this Manual, the Intermediary Manual, or the Medicare Carrier Manual, it is up to the Medicare carrier or intermediary to make the coverage decision. This is done in consultation with its medical staff and the Center for Medicare and Medicaid Services (CMS), and is based on the law, regulations, rulings and general program instructions.

The following list identifies the CMS National Coverage Determinations (NCDs) that may be directly related to services, equipment, and/or supplies associated with physical therapy, occupational therapy, and/or speech-language pathology services. By clicking on the underlined text, the user will be taken to that part of this document where the actual text of the NCD can be read.

35-2 Manipulation

35-3 Heat treatment, including the use of diathermy and ultrasound for pulmonary

	conditions
35-8	Acupuncture
35-10	Hyperbaric oxygen therapy
35-14	Consultations with a beneficiary's family and associates
35-15	Postural drainage procedures and pulmonary exercises
35-20	Treatment of motor function disorders with electric nerve stimulation
35-21	Inpatient hospital pain rehabilitation programs
35-21.1	Outpatient hospital pain rehabilitation programs
35-25	Cardiac rehabilitation programs
35-26	Treatment of obesity
35-27	Biofeedback therapy
35-27.1	Biofeedback therapy for the treatment of urinary incontinence
35-31	Treatment of decubitus ulcers ***Note*** See Program Memorandum AB-00-53 June 2000 related to coverage of electrostimulation in the treatment of wounds.
35-41	Diathermy treatment
35-46	Assessing patient's suitability for electrical nerve stimulation therapy
35-52	Laser procedures
35-56	Fluidized therapy dry heat for certain musculoskeletal disorders
35-66	Treatment of psoriasis
35-72	Electrotherapy for treatment of facial nerve paralysis (Bell's Palsy)
35-74	External counterpulsation (ECP) for severe angina
35-77	Neuromuscular electrical stimulation (NMES) in the treatment of disuse atrophy
35-89	Speech pathology services for the treatment of dysphagia
35-92	Transcendental meditation
35-97	Vertebral axial decompression (VAX-D)
35-98	Electrostimulation in the treatment of wounds ***Note***35-98 non-coverage determination is currently suspended per Program Memorandum AB-00-53 June 2000
45-1	L-DOPA
45-15	Physician's office within an institution – coverage of services and supplies incident to a physician's services
45-19	Transcutaneous electrical nerve stimulation (TENS) for acute post-operative pain
45-25	Supplies used in the delivery of transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES)
60-3	White cane for use by a blind person
60-4	Home use of oxygen
60-5	Power-operated vehicles that may be used as wheelchairs
60-6	Specially sized wheelchairs
60-8	Seat lift
60-9	Durable medical equipment reference list

60-15	Safety roller
60-16	Pneumatic compression devices (used for lymphedema)
60-18	Hospital beds
60-19	Air-fluidized bed
60-20	Transcutaneous electrical nerve stimulators (TENS)
60-21	Intrapulmonary percussive ventilator (IPV)
60-23	Speech generating devices
60-24	Non-implantable pelvic floor electrical stimulator
65-2	Electrical continence aid
65-5	Electronic speech aids
65-8	Electrical nerve stimulators
65-9	Incontinence control devices
70-3	Prosthetic shoe
80-1	Institutional and home care patient education programs

******

35-2 MANIPULATION *[contents]*

A. Manipulation of the Rib Cage.--Manual manipulation of the rib cage contributes to the treatment of respiratory conditions such as bronchitis, emphysema, and asthma as part of a regimen which includes other elements of therapy, and is covered only under such circumstances.
B. Manipulation of the Head.--Manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck is a covered service.

35-3 HEAT TREATMENT, INCLUDING THE USE OF DIATHERMY AND ULTRA-SOUND FOR PULMONARY CONDITIONS--NOT COVERED *[contents]*

There is no physiological rationale or valid scientific documentation of effectiveness of diathermy or ultrasound heat treatments for asthma, bronchitis, or any other pulmonary condition and for such purpose this treatment cannot be considered reasonable and necessary within the meaning of section 1862(a)(1) of the law.

Cross-refer: §35-41

35-8 ACUPUNCTURE--NOT COVERED *[contents]*

Although acupuncture has been used for thousands of years in China and for decades in parts of Europe, it is a new agent of unknown use and efficacy in the United States. Even in those areas of the world where it has been widely used, its mechanism is not known. Three units of the

National Institutes of Health, the National Institute of General Medical Sciences, National Institute of Neurological Diseases and Stroke, and Fogarty International Center have been designed to assess and identify specific opportunities and needs for research attending the use of acupuncture for surgical anesthesia and relief of chronic pain. Until the pending scientific assessment of the technique has been completed and its efficacy has been established, Medicare reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes, may not be made. Accordingly, acupuncture is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

35-10 HYPERBARIC OXYGEN THERAPY *[contents]*

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A. Covered Conditions.--Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:
    1. Acute carbon monoxide intoxication, (ICD-9 -CM diagnosis 986).
    2. Decompression illness, (ICD-9-CM diagnosis 993.2, 993.3).
    3. Gas embolism, (ICD-9-CM diagnosis 958.0, 999.1).
    4. Gas gangrene, (ICD-9-CM diagnosis 0400).
    5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened. (ICD-9-CM diagnosis 902.53, 903.01, 903.1, 904.0, 904.41.)
    6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened. (ICD-9-CM diagnosis 927.00-927.03, 927.09-927.11, 927.20-927.21, 927.8-927.9, 928.00-928.01, 928.10-928.11, 928.20-928.21, 928.3, 928.8-928.9, 929.0, 929.9, 996.90- 996.99.)
    7. Progressive necrotizing infections (necrotizing fasciitis), (ICD-9-CM diagnosis 728.86).
    8. Acute peripheral arterial insufficiency, (ICD-9-CM diagnosis 444.21, 444.22, 444.81).
    9. Preparation and preservation of compromised skin grafts (not for primary management of wounds), (ICD-9CM diagnosis 996.52; excludes artificial skin graft).
    10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, (ICD-9-CM diagnosis 730.10-730.19).
    11. Osteoradionecrosis as an adjunct to conventional treatment, (ICD-9-CM diagnosis 526.89).

12. Soft tissue radionecrosis as an adjunct to conventional treatment, (ICD-9-CM diagnosis 990).
13. Cyanide poisoning, (ICD-9-CM diagnosis 987.7, 989.0).
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment, (ICD-9-CM diagnosis 039.0-039.4, 039.8, 039.9).

C. Noncovered Conditions.--All other indications not specified under §35-10 (A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in § 35-10 (A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
21. Acute cerebral edema.

D. Reasonable Utilization Parameters.--Make payment where HBO therapy is clinically practical. HBO therapy should not be a replacement for other standard successful therapeutic measures. Depending on the response of the individual patient and the severity of the original problem, treatment may range from less than 1 week to several months duration, the average being 2 to 4 weeks. Review and document the medical necessity for use of hyperbaric oxygen for more than 2 months, regardless of the condition of the patient, before further reimbursement is made.

Topical Application of Oxygen.--This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen. (Cross refer: §35-31.)

35-14 CONSULTATIONS WITH A BENEFICIARY'S FAMILY AND ASSOCIATES

[contents]

In certain types of medical conditions, including when a patient is withdrawn and uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts his patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. If the beneficiary is not an inpatient of a hospital, Part B reimbursement for such an interview is subject to the special limitation on payments for physicians' services in connection with mental, psychoneurotic, and personality disorders.

A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition. For example, two situations where family counseling services would be appropriate are as follows: (1) where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient. While to a limited degree, the counseling described in the second situation may be used to modify the behavior of the family members, such services nevertheless are covered because they relate primarily to the management of the patient's problems and not to the treatment of the family member's problems.

See Medicare Intermediary Manual, §3212; Medicare Carriers Manual, §§2020, and 2470-2476.2; *(Note: Section 2476.2 is not present in the current version of the Medicare Carriers Manual)* and Hospital Manual, §160.1.

35-15 POSTURAL DRAINAGE PROCEDURES AND PULMONARY EXERCISES

[contents]

In most cases, postural drainage procedures and pulmonary exercises can be carried out safely and effectively by nursing personnel. However, in some cases patients may have acute or severe pulmonary conditions involving complex situations in which these procedures or exercises require the knowledge and skills of a physical therapist or a respiratory therapist. Therefore, if the attending physician determines as part of his/her plan of treatment that for the safe and

effective administration of such services the procedures or exercises in question need to be performed by a physical therapist, the services of such a therapist constitute covered physical therapy when provided as an inpatient hospital service, extended care service, home health service, or outpatient physical therapy service.

NOTE: Physical therapy furnished in the outpatient department of a hospital is covered under the outpatient physical therapy benefit.

If the attending physician determines that the services should be performed by a respiratory therapist, the services of such a therapist constitute covered respiratory therapy when provided as an inpatient hospital service, outpatient hospital service, or extended care service, assuming that such services are furnished to the skilled nursing facility by a hospital with which the facility has a transfer agreement. Since the services of a respiratory therapist are not covered under the home health benefit, payment may not be made under the home health benefit for visits by a respiratory therapist to a patient's home to provide such services. Postural drainage procedures and pulmonary exercises are also covered when furnished by a physical therapist or a respiratory therapist as incident to a physician's professional service.

See Medicare Intermediary Manual, §§3112, 3116, and 3133.90 and Medicare Carriers Manual, §2050.2.

35-20 TREATMENT OF MOTOR FUNCTION DISORDERS WITH ELECTRIC NERVE STIMULATION-NOT COVERED *[contents]*

While electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary.

See §§35-27 and 65-8.

NOTE: Medicare coverage of deep brain stimulation by implantation of a stimulator device is not prohibited. Therefore, coverage of deep brain stimulation provided by an implanted deep brain stimulator is at the carrier's discretion.

35-21 INPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS *[contents]*

Pain rehabilitation programs are a relatively new and innovative approach to the treatment of intractable pain. The goal of such programs is to give a patient the tools to manage and control his/her pain and thereby improve his/her ability to function independently.

A hospital level pain rehabilitation program is one that employs a coordinated multidisciplinary team to deliver, in a controlled environment, a concentrated program which is designed to modify pain behavior through the treatment of the physiological, psychological, and social aspects of pain. Such programs generally include diagnostic testing, skilled nursing, psychotherapy, structured progressive withdrawal from pain medications, physical therapy and occupational therapy to restore physical fitness (mobility and endurance) to a maximal level within the constraints of a patient's physical disability, and the use of mechanical devices and/or activities to relieve pain or modify a patient's reaction to it (e.g., nerve stimulator, hydrotherapy, massage, ice, systemic muscle relaxation training, and diversional activities). The nurse's responsibility in such pain rehabilitation programs is to observe and assess, on a continuing basis, a patient's condition and response to the program as reflected by his actions while in the nursing unit, and to assure that the atmosphere within the unit is not supportive of pain behavior. The day-to-day activities involved in carrying out the program are under the general supervision and, as needed, direct supervision of a physician.

Since pain rehabilitation programs of a lesser scope than that described above would raise a question as to whether the program could be provided in a less intensive setting than on an inpatient hospital basis, carefully evaluate such programs to determine whether the program does, in fact, necessitate a hospital level of care. Some pain rehabilitation programs may utilize services and devices which are excluded from coverage, e.g., acupuncture (see §35-8), biofeedback (see §35-27), dorsal column stimulator (see §65-8), and family counseling services (see §35-l4). In determining whether the scope of a pain program does necessitate inpatient hospital care, evaluate only those services and devices which are covered. Although diagnostic tests may be an appropriate part of pain rehabilitation programs, such tests would be covered in an individual case only where they can be reasonably related to a patient's illness, complaint, symptom, or injury and where they do not represent an unnecessary duplication of tests previously performed.

An inpatient program of 4 weeks' duration is generally required to modify pain behavior. After this period it would be expected that any additional rehabilitation services which might be required could be effectively provided on an outpatient basis under an outpatient pain rehabilitation program (see §35-21.1sf2) or other outpatient program. The first 7-l0 days of such an inpatient program constitute, in effect, an evaluation period. If a patient is unable to adjust to the program within this period, it is generally concluded that it is unlikely that the program will be effective and the patient is discharged from the program. On occasions a program longer than 4 weeks may be required in a particular case. In such a case there should be documentation to substantiate that inpatient care beyond a 4-week period was reasonable and necessary. Similarly, where it appears that a patient participating in a program is being granted frequent outside

passes, a question would exist as to whether an inpatient program is reasonable and necessary for the treatment of the patient's condition.

An inpatient hospital stay for the purpose of participating in a pain rehabilitation program would be covered as reasonable and necessary to the treatment of a patient's condition where the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain. Chronic pain patients often have psychological problems which accompany or stem from the physical pain and it is appropriate to include psychological treatment in the multidisciplinary approach. However, patients whose pain symptoms result from a mental condition, rather than from any physical cause, generally cannot be successfully treated in a pain rehabilitation program.

35-21.1 OUTPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS
[contents]

Some hospitals also provide pain rehabilitation programs for outpatients. In such programs, services frequently are provided in group settings even though they are being furnished pursuant to each patient's individualized plan of treatment.

Coverage of services furnished under outpatient hospital pain rehabilitation programs, including services furnished in group settings under individualized plans of treatment, is available if the patient's pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by the patient to function independently has resulted from the pain. If a patient meets these conditions and the program provides services of the types discussed in §35-21 the services provided under the program may be covered. Noncovered services (e.g., vocational counseling, meals for outpatients, or acupuncture) continue to be excluded from coverage, and intermediaries would not be precluded from finding, in the case of particular patients, that the pain rehabilitation program is not reasonable and necessary under §1862(a)(1) of the law for the treatment of their conditions.

35-25 CARDIAC REHABILITATION PROGRAMS. *[contents]*

A. General.--Exercise programs for cardiac patients, commonly referred to as cardiac rehabilitation programs, are increasingly being conducted in specialized, freestanding, cardiac rehabilitation clinics as well as in outpatient hospital departments. Exercise programs include specific types of exercise, individually prescribed for each patient.

   Medicare coverage of cardiac rehabilitation programs are considered reasonable and necessary only for patients with a clear medical need, who are referred by their attending physician and (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; and/or (3) have stable angina pectoris.

Cardiac rehabilitation programs may be provided either by the outpatient department of a hospital or in a physician-directed clinic. Coverage for either program is subject to the following conditions:

- The facility meets the definition of a hospital outpatient department or a physician- directed clinic, i.e., a physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician;
- The facility has available for immediate use all the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator;
- The program is conducted in an area set aside for the exclusive use of the program while it is in session;
- The program is staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. Services of nonphysician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible. The examples below are for illustration purposes only. They are not meant to limit the discretion of the contractor to make determinations in this regard.

  - The case in which a contractor determines that the presence of a physician in an office across the hall from the exercise room who is available at all times for an emergency meets the requirement that the physician is immediately available and accessible; or

  - The case in which a contractor determines that the presence of a physician in a building other than that containing the exercise room does not meet the requirement that the physician is immediately available and accessible; and

- The nonphysician personnel are employees of either the physician, hospital, or clinic conducting the program and their services are "incident-to a physician's professional services."

Contractors need not undertake elaborate or costly monitoring activities to determine whether these requirements are met, but need only satisfy themselves to the extent that they ordinarily do in connection with, for example, the requirements for coverage of services in physician-directed

clinics. (See Medicare Carriers Manual, §2050.4 *(Note: Section 2050.4 is not present in the current version of the Medicare Carriers Manual)*; (Intermediary Manual, §3112.4A; Hospital Manual, §230.4.)

In addition to the conditions listed above, coverage for cardiac rehabilitation programs furnished by hospitals to outpatients is also subject to the rules described in the Intermediary Manual, §3112.4 and the Hospital Manual, §230.4. Reasonable charge reimbursement for these services which are performed in "freestanding" clinics are subject to the limitations set forth in the Medicare Carriers Manual, §5241 *(Note: Section 5241 is not present in the current version of the Medicare Carriers Manual).*

Diagnostic Testing - Stress Testing.--A prospective candidate for a cardiac rehabilitation program must be evaluated for his suitability to participate. A valuable diagnostic test for this purpose is the stress test. The program need not necessarily include a stress test, but may accept one performed by the patient's attending physician. Stress testing performed in the outpatient department of a hospital or in a physician-directed clinic may be covered when reasonable and necessary for one or more of the following:

- Evaluation of chest pain, especially atypical chest pain;
- Development of exercise prescriptions for patients with known cardiac disease; and/or
- Pre and postoperative evaluation of patients undergoing coronary artery by-pass procedures.

Refer to subsection E, Utilization Screens, for the acceptable frequency of stress testing performed during an individual's exercise program.

ECG Rhythm Strips. ECG rhythm strips (and other ECG monitoring) constitute an important and necessary procedure which should be done periodically while a cardiac patient is engaged in a physician-controlled exercise program. See subsection E, Utilization Screens, for allowable screens.

C. Other Diagnostic and Therapeutic Services.--A freestanding or hospital based cardiac rehabilitation clinic may also provide diagnostic and therapeutic services other than stress testing and ECG monitoring. Any such other services must meet the usual coverage requirements for the specific service, e.g., the incident-to, and reasonable and necessary requirements.
    1. Psychotherapy and Psychological Testing.--It would not normally be considered reasonable and necessary to provide psychotherapy to all cardiac rehabilitation patients, or even to test all such patients to determine whether they may have a mental, psychoneurotic, or personality disorder. However, where a patient has a

diagnosed mental, psychoneurotic, or personality disorder, psychotherapy furnished by a psychiatrist--or by a psychologist rendering such services incident to a physician's professional service--may be covered. Similarly, diagnostic testing of a cardiac rehabilitation patient for a mental problem may be covered where the patient shows appropriate symptoms, e.g., excessive anxiety or fear associated with the cardiac disease.

2. Physical and Occupational Therapy.--Physical therapy and occupational therapy would not be covered when furnished in connection with cardiac rehabilitation exercise program services covered under this section unless there also is a diagnosed noncardiac condition requiring such therapy, e.g., where a patient who is just recuperating from an acute phase of heart disease may have had a stroke which would require physical and/or occupational therapy. (While the cardiac rehabilitation exercise program may by some be considered a form of physical therapy, it is a specialized program conducted and/or supervised by specially trained personnel whose services are performed under the direct supervision of a physician.) Restrictions on coverage of physical therapy and occupational therapy under this section do not affect rules regarding coverage or noncoverage of such services when furnished in a hospital inpatient or outpatient setting.

(See Intermediary Manual, §3101.9 and Hospital Manual, §210.9.)

3. Patient Education Services.--Many cardiac rehabilitation programs provide health education in the form of lectures or counseling in which patients and/or family members are given information, e.g., on diet, nutrition, and sexual activity to assist them in adjusting their living habits because of the cardiac condition. However, the same kind of information would have been furnished to a patient and/or family members by the attending physician following the patient's acute cardiac episode. Therefore, formal lectures and counseling on these subjects are not considered reasonable and necessary as a separately identifiable service when provided as a part of a cardiac rehabilitation exercise program. In addition, where a freestanding cardiac rehabilitation clinic provides board and room for the patient (and in some cases family members), these services are not covered under Medicare.
4. Duration of the Program.--Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions, usually 3 sessions a week in a single 12 week period. Coverage for continued participation in cardiac exercise programs beyond 12 weeks would be allowed only on a case-by-case basis with exit criteria taken into consideration.

Although firm exit criteria for terminating the therapeutic outpatient exercise treatment and rehabilitation program have not been established, the following guidelines have been identified as acceptable:

- The patient has achieved a stable level of exercise tolerance without ischemia or dysrhythmia;
- Symptoms of angina or dyspnea are stable at the patient's maximum exercise level;
- Patient's resting blood pressure and heart rate are within normal limits; or
- The stress test is not positive during exercise. (A positive test in this context implies an ECG with a junctional depression of 2mm or more associated with slowly rising, horizontal, or down sloping ST segment.)

Accordingly, claims for coverage of cardiac rehabilitation exercise programs beyond 12 weeks are reviewed by the contractors' medical consultants. When claims are accompanied by acceptable documentation that the patient has not reached an exit level, coverage may be extended, but should not exceed a maximum of 24 weeks.

E. Utilization Screens.--Patients who participate in cardiac rehabilitation programs will require certain services more frequently than other patients being treated on an outpatient basis. Therefore, in order to provide coverage in a uniform manner, the following utilization screens should be implemented in addition to existing screens for any cardiac rehabilitation services not listed:
    1. Group 1 Services
        - Continuous ECG telemetric monitoring during exercise;
        - ECG rhythm strip with interpretation and physician's revision of exercise prescription; and
        - Limited examination for physician follow-up to adjust medication or other treatment changes.

A visit including one or more of this range of routine services is considered as one routine cardiac rehabilitation visit. In order for the visit to be reimbursable, at least one of the Group 1 services must be performed. The same rate of reimbursement would be allowed for each visit, but not all the services need be performed at each visit.

Allow a maximum of three visits per week.

    2. Group 2 Services
        - New patient comprehensive evaluation, including history, physical, and preparation of initial exercise prescription.

Allow one at the beginning of the program if not already performed by the patient's attending physician, or if that performed by the patient's attending physician is not acceptable to the program's director.

        - ECG stress test (treadmill or bicycle ergometer) with physician monitoring and report.

Allow one at the beginning of the program and one after 3 months (usually the completion of the program).

- Other physician services, as needed.

35-26 TREATMENT OF OBESITY *[contents]*

Obesity itself cannot be considered an illness. The immediate cause is a caloric intake which is persistently higher than caloric output. Program payment may not be made for treatment of obesity alone since this treatment is not reasonable and necessary for the diagnosis or treatment of an illness or injury. However, although obesity is not in itself an illness, it may be caused by illnesses such as hypothyroidism, Cushing's disease, and hypothalamic lesions. In addition, obesity can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Therefore, services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these illnesses.

Cross refer: CIM 35-33 and 35-40

35-27 BIOFEEDBACK THERAPY *[contents]*

Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured.

Biofeedback therapy differs from electromyography, which is a diagnostic procedure used to record and study the electrical properties of skeletal muscle. An electromyography device may be used to provide feedback with certain types of biofeedback.

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions. (See HCFA-Pub. 14-3, §§2200ff, 2215, and 4161; HCFA-Pub. 13-3, §§3133.3, 3148, and 3149 *(Note: Section 3149 is not present in the current version of the Intermediary Manual)*; HCFA-Pub. 10, §§242 and 242.5 for special physical therapy requirements. See also §35-20 and 65-8.)

35-27.1 BIOFEEDBACK THERAPY FOR THE TREATMENT OF URINARY INCONTINENCE *[contents]*

Biofeedback therapy for the treatment of urinary incontinence (Effective for services performed on or after July 1, 2001.) This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting.
Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.
Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback-assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor
musculature and to assist patients in the performance of PME. A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.
Contractors may decide whether or not to cover biofeedback as an initial treatment modality.
Home use of biofeedback therapy is not covered.

35-31 TREATMENT OF DECUBITUS ULCERS *[contents]*

An accepted procedure for healing decubitus ulcers is to remove dead tissue from the lesions and to keep them clean to promote the growth of new tissue. This may be accomplished by hydrotherapy (whirlpool) treatments. Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients when treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program. Some examples of these types of treatments are: ultraviolet light, low intensity direct current, topical application of oxygen, and topical dressings with Balsam of Peru in castor oil.

See Program Memorandum AB-00-53 for current electrostimulation coverage

35-4l DIATHERMY TREATMENT *[contents]*

High energy pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy. Accordingly, where the contractor's medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services. Further, when the charge for covered pulsed wave diathermy treatment is substantially in excess of that which is reasonable for standard diathermy, payment

is based on the reasonable charge for standard diathermy (CPT-4 code 97024, ICD-9-CM code 93.34).

Cross-refer: §35-3

35-46 ASSESSING PATIENT'S SUITABILITY FOR ELECTRICAL NERVE STIMULATION THERAPY *[contents]*

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation (TENS) --This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §45-25 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain. (See §35-46B.)

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS unit from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS unit as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. Percutaneous Electrical Nerve Stimulation (PENS).--This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's

service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §65-8 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §60-20 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

35-52 LASER PROCEDURES *[contents]*

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

35-56 FLUIDIZED THERAPY DRY HEAT FOR CERTAIN MUSCULOSKELETAL DISORDERS *[contents]*

Fluidized therapy is a high intensity heat modality consisting of a dry whirlpool of finely divided solid particles suspended in a heated air stream, the mixture having the properties of a liquid. Use of fluidized therapy dry heat is covered as an acceptable alternative to other heat therapy modalities in the treatment of acute or subacute traumatic or nontraumatic musculoskeletal disorders of the extremities.

35-66 TREATMENT OF PSORIASIS *[contents]*

Psoriasis is a chronic skin disease, for which several conventional methods of treatment have been recognized as covered. These include topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).

A newer treatment for psoriasis uses a psoralen derivative drug in combination with ultraviolet A light, known as PUVA. PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. The contractor should document this before paying for PUVA therapy.

In addition, reimbursement for PUVA therapy should be limited to amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

35-72 ELECTROTHERAPY FOR TREATMENT OF FACIAL NERVE PARALYSIS (BELL'S PALSY).--NOT COVERED. *[contents]*

Electrotherapy for the treatment of facial nerve paralysis, commonly known as Bell's Palsy, is not covered under Medicare because its clinical effectiveness has not been established.

Electrotherapy for the treatment of facial nerve paralysis is the application of electrical stimulation to affected facial muscles to provide muscle innervation with the intention of preventing muscle degeneration. A device that generates an electrical current with controlled frequency, intensity, wave form and type (galvanic or faradic) is used in combination with a pad electrode and a hand applicator electrode to provide electrical stimulation.

35-74 EXTERNAL COUNTERPULSATION (ECP) FOR SEVERE ANGINA—COVERED *[contents]*

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although these and similar devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, Medicare coverage is limited

to its use in patients with stable angina pectoris, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Other uses of this device and similar devices remain non-covered. In addition, the non-coverage of hydraulic versions of these types of devices remains in force.

Coverage is provided for the use of ECP for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because: (1) their condition is inoperable, or at high risk of operative complications or post-operative failure; (2) their coronary anatomy is not readily amenable to such procedures; or (3) they have co-morbid states which create excessive risk.

A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs, which inflate and deflate in synchronization with the patient's cardiac cycle.

During diastole the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole, which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to two years.

This procedure must be done under direct supervision of a physician.

35-77 NEUROMUSCULAR ELECTRICAL STIMULATION (NMES) IN THE TREATMENT OF DISUSE ATROPHY (Effective for services performed on and after 11-5-84.) *[contents]*

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. Coverage of NMES is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse

are causing atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See §45-25 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)

35-89 SPEECH PATHOLOGY SERVICES FOR THE TREATMENT OF DYSPHAGIA (Effective for services performed on and after 08/28/89) *[contents]*

Dysphagia is a swallowing disorder that may be due to various neurological, structural, and cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, and encephalopathies. While dysphagia can afflict any age group, it most often appears among the elderly. Speech pathology services are covered under Medicare for the treatment of dysphagia, regardless of the presence of a communication disability.

Patients who are motivated, moderately alert, and have some degree of deglutition and swallowing functions are appropriate candidates for dysphagia therapy. Elements of the therapy program can include thermal stimulation to heighten the sensitivity of the swallowing reflex, exercises to improve oral-motor control, training in laryngeal adduction and compensatory swallowing techniques, and positioning and dietary modifications. Design all programs to ensure swallowing safety of the patient during oral feedings and maintain adequate nutrition.

Cross-refer: Intermediary Manual, §3101.l0A; Medicare Carriers Manual, §2216; Hospital Manual, §210.11; Home Health Agency Manual, §205.2C; Skilled Nursing Facility Manual, §230.3B; Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual, §205.6 *(Note: Section 205.6 is not present in the current version of the OPT/CORF Manual)*.

35-92 TRANSCENDENTAL MEDITATION - NOT COVERED *[contents]*

Transcendental meditation (TM) is a skill that is claimed to produce a state of rest and relaxation when practiced effectively. Typically, patients are taught TM techniques over the course of several sessions by persons trained in TM. The patient then uses the TM technique on his or her own to induce the relaxed state. Proponents of TM have urged that Medicare cover the training of patients to practice TM when it is medically prescribed as treatment for mild hypertension, as adjunctive therapy in the treatment of essential hypertension, or as the sole or adjunctive treatment of anxiety and other psychological stress-related disorders.

After review of this issue, HCFA has concluded that the evidence concerning the medical efficacy of TM is incomplete at best and does not demonstrate effectiveness and that a professional level of skill is not required for the training of patients to engage in TM.

Although many articles have been written about application of TM for patients with certain forms of hypertension and anxiety, there are no rigorous scientific studies that demonstrate the effectiveness of TM for use as an adjunct medical therapy for such conditions. Accordingly, neither TM nor the training of patients for its use are covered under the Medicare program.

35-97 VERTEBRAL AXIAL DECOMPRESSION (VAX-D) - NOT COVERED

[contents]

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

35-98 ELECTROSTIMULATION IN THE TREATMENT OF WOUNDS - NOT COVERED

[contents]

Electrical stimulation (ES) has been used or studied for many different applications, one of which is accelerating wound healing. The types of ES used for healing chronic venous and arterial wound and pressure ulcers are direct current (DC), alternating current (AC), pulsed current (PC), pulsed electromagnetic induction (PEMI), and spinal cord stimulation (SCS). An example of AC is transcutaneous electrical stimulation (TENS). The PEMI includes Pulsed Electromagnetic Field (PEMF) and Pulsed Electromagnetic Energy (PEE) using pulsed radio frequency energy, both of which are nonthermal i.e., they do not produce heat. Some ES use generators to create energy in the radio frequency band, delivered in megahertz (MHz). They typically deliver energy by contacting means such as coils, rather than by leads or surface electrodes.

There is insufficient evidence to determine any clinically significant differences in healing rates. Therefore, ES cannot be covered by Medicare because its effectiveness has not been adequately demonstrated.

Transmittal No. AB-00-53 Date JUNE 2000

[contents]

> PROGRAM MEMORANDUM
> INTERMEDIARIES/CARRIERS
> Department of Health and Human Services
> Health Care Financing Administration
> Transmittal No. AB-00-53 Date JUNE 2000
>
> This Program Memorandum re-issues Program Memorandum AB-99-52; Change Request 577 dated July 1999. The only change is the discard date and the contact person; all other material remains the same.

This Program Memorandum re-issues Program Memorandum AB-98-44; Change Request 577 dated August 1998. The only change is the discard date and the contact person; all other material remains the same.
Change Request #577

SUBJECT: Suspension of National Coverage Policy on Electrostimulation for Wound Healing

Program Memorandums B-97-11, dated December, 1997 and AB-98-2, dated February 1998, notified you of the court's decision in Aitken v. Shalala. This court order precludes HCFA and its agents from giving any effect to the national coverage determination published in Medicare Coverage Issues Manual (MCIM) §35-98. This section provided that the cost of treatment to promote the healing of open wounds by means of electrical stimulation therapy would not qualify for reimbursement under Medicare. The court has enjoined HCFA and its agents from enforcing or giving effect to MCIM §35-98. The previous PMs on this subject carried a discard date of June 1998, in anticipation that we would be able to resolve the concerns of the court quickly. However, the court order remains in effect. Therefore, continue to ensure that all claims for electrical stimulation are processed as if the national coverage determination described in MCIM §35-98 had never existed, in accordance with the court's order. This includes claims for services performed after July 14, 1997, resubmitted based upon a denial pursuant to the national coverage determination.
These instructions should be implemented within your current operating budget.
This Program Memorandum may be discarded June 30, 2001. |
For further information, contact John Whyte, M.D. at (410) 786-9668.
HCFA-Pub. 60AB

45-1 L-DOPA *[contents]*

A. Part A Payment for L-Dopa and Associated Inpatient Hospital Services.--A hospital stay and related ancillary services for the administration of L-Dopa are covered if medically required for this purpose. Whether a drug represents an allowable inpatient hospital cost during such stay depends on whether it meets the definition of a drug in §1861(t) of the Act; i.e., on its inclusion in the compendia named in the Act or approval by the hospital's pharmacy and drug therapeutics (P&DT) or equivalent committee. (Levodopa (L-Dopa) has been favorably evaluated for the treatment of Parkinsonism by A.M.A. Drug Evaluations, First Edition 1971, the replacement compendia for "New Drugs.")

Inpatient hospital services are frequently not required in many cases when L-Dopa therapy is initiated. Therefore, determine the medical need for inpatient hospital services on the basis of medical facts in the individual case. It is not necessary to hospitalize the typical, well-functioning, ambulatory Parkinsonian patient who has no concurrent disease at the start of L-Dopa treatment. It is reasonable to provide inpatient hospital services for Parkinsonian patients

with concurrent diseases, particularly of the cardiovascular, gastrointestinal, and neuropsychiatric systems. Although many patients require hospitalization for a period of under 2 weeks, a 4-week period of inpatient care is not unreasonable.

Laboratory tests in connection with the administration of L-Dopa.--The tests medically warranted in connection with the achievement of optimal dosage and the control of the side effects of L-Dopa include a complete blood count, liver function tests such as SGOT, SGPT, and/or alkaline phosphatase, BUN or creatinine and urinalysis, blood sugar, and electrocardiogram.

Whether or not the patient is hospitalized, laboratory tests in certain cases are reasonable at weekly intervals although some physicians prefer to perform the tests much less frequently.

Physical therapy furnished in connection with administration of L-Dopa.--Where, following administration of the drug, the patient experiences a reduction of rigidity which permits the reestablishment of a restorative goal for him/her, physical therapy services required to enable him/her to achieve this goal are payable provided they require the skills of a qualified physical therapist and are furnished by or under the supervision of such a therapist. However, once the individual's restoration potential has been achieved, the services required to maintain him/her at this level do not generally require the skills of a qualified physical therapist. In such situations, the role of the therapist is to evaluate the patient's needs in consultation with his/her physician and design a program of exercise appropriate to the capacity and tolerance of the patient and treatment objectives of the physician, leaving to others the actual carrying out of the program. While the evaluative services rendered by a qualified physical therapist are payable as physical therapy, services furnished by others in connection with the carrying out of the maintenance program established by the therapist are not.

See Intermediary Manual, §3101.3 and Medicare Carriers Manual, §2050.5. *(Note: Section 2050.5 is not present in the current version of the Medicare Carriers Manual).*

B. Part A Reimbursement for L-Dopa Therapy in SNFs.--Initiation of L-Dopa therapy can be appropriately carried out in the SNF setting, applying the same guidelines used for initiation of L-Dopa therapy in the hospital, including the types of patients who should be covered for inpatient services, the role of physical therapy, and the use of laboratory tests. (See subsection A.)

Where inpatient care is required and L-Dopa therapy is initiated in the SNF, limit the stay to a maximum of 4 weeks; but in many cases the need may be no longer than 1 or 2 weeks, depending upon the patient's condition. However, where L-Dopa therapy is begun in the hospital and the patient is transferred to an SNF for continuation of the therapy, a combined length of stay in hospital and SNF of no longer than 4 weeks is reasonable (i.e., 1 week hospital stay followed by 3 weeks SNF stay; or 2 weeks hospital stay followed by 2 weeks SNF stay; etc.). Medical need must be demonstrated in cases where the combined length of stay in hospital and SNF is

longer than 4 weeks. The choice of hospital or SNF, and the decision regarding the relative length of time spent in each, should be left to the medical judgment of the treating physician.

See Intermediary Manual, §3133.5

C. L-Dopa Coverage Under Part B.--Part B reimbursement may not be made for the drug L-Dopa since it is a self-administrable drug. (See Intermediary Manual, §3112.4B; Medicare Carriers Manual, §2050.5B *(Note: Section 2050.5B is not present in the current version of the Medicare Carriers Manual);* and Hospital Manual, §230.4B.) However, physician services rendered in connection with its administration and control of its side effects are covered if determined to be reasonable and necessary. Initiation of L-Dopa therapy on an outpatient basis is possible in most cases. Visit frequency ranging from every week to every 2 or 3 months is acceptable. However, after half a year of therapy, visits more frequent than every month would usually not be reasonable.

45-15 PHYSICIAN'S OFFICE WITHIN AN INSTITUTION--COVERAGE OF SERVICES AND SUPPLIES INCIDENT TO A PHYSICIAN'S SERVICES *[contents]*

Where a physician establishes an office within a nursing home or other institution, coverage of services and supplies furnished in the office must be determined in accordance with the "incident to a physician's professional service" provision (see Intermediary Manual, §3112.4A or Medicare Carriers Manual, §2050.1), as in any physician's office. A physician's office within an institution must be confined to a separately identified part of the facility which is used solely as the physician's office and cannot be construed to extend throughout the entire institution. Thus, services performed outside the "office" area would be subject to the coverage rules applicable to services furnished outside the office setting.

In order to accurately apply the criteria in §3112.4 or §2050.l, give consideration to the physical proximity of the institution and physician's office. When his office is located within a facility, a physician may not be reimbursed for services, supplies, and use of equipment which fall outside the scope of services "commonly furnished" in physician's offices generally, even though such services may be furnished in his institutional office. Additionally, make a distinction between the physician's office practice and the institution, especially when the physician is administrator or owner of the facility. Thus, for their services to be covered under the criteria in §3112.4A or §2050.l, the auxiliary medical personnel must be members of the office staff rather than of the institution's staff, and the cost of supplies must represent an expense to the physician's office practice. Finally, services performed by the employees of the physician outside the "office" area must be directly supervised by the physician; his presence in the facility as a whole would not suffice to meet this requirement. (In any setting, of course, supervision of auxiliary personnel in and of itself is not considered a "physician's professional service" to which the services of the auxiliary personnel could be an incidental part, i.e., in addition to supervision, the physician must perform or have performed a personal professional service to the patient to which the services of

the auxiliary personnel could be considered an incidental part). Denials for failure to meet any of these requirements would be based on §l861(s)(2)(A) of the Act.

Establishment of an office within an institution would not modify rules otherwise applicable for determining coverage of the physician's personal professional services within the institution. However, in view of the opportunity afforded to a physician who maintains such an office for rendering services to a sizable number of patients in a short period of time or for performing frequent services for the same patient, claims for physicians' services rendered under such circumstances would require careful evaluation by the carrier to assure that payment is made only for services that are reasonable and necessary.

Cross-refer: Intermediary Manual, §3112.4A; Medicare Carriers Manual, §2050.1

45-19 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) FOR ACUTE POST-OPERATIVE PAIN *[contents]*

The use of transcutaneous electrical nerve stimulation (TENS) for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery.

TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician's service when furnished in connection with surgery done on an outpatient basis, and covered under Part B.

It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In cases when TENS is used for longer periods, contractors should attempt to ascertain whether TENS is no longer being used for acute pain but rather for chronic pain, in which case the TENS device may be covered as durable medical equipment as described in §60-20.

Cross-refer: HCFA Pub. 13-3, §§65-8, 3101.4, 3112.4, 3113; HCFA Pub. 14-3, §§65-8, 2050.1, 2100; HCFA Pub. 10, §§65-8, 210.4, 230, 235 *(Note: Section 235 is not present in the current version of the Hospital Manual).*

45-25 SUPPLIES USED IN THE DELIVERY OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) AND NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)--(Effective for services rendered (i.e., items rented or purchased) on or after July 14, 1988.) *[contents]*

Transcutaneous Electrical Nerve Stimulation (TENS) and/or Neuromuscular Electrical

Stimulation (NMES) can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;

2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and

3. One of the medical indications outlined below is met:

    - The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;

    - The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;

    - The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;

    - The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or

    - The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §35-46 unless:

4. The patient has a documented skin problem prior to the start of the trial period; and

5. The carrier's medical consultants are satisfied that use of such an item is medically necessary for the patient.

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§35-46 and 60-20 and the use of NMES in the treatment of disuse atrophy in §35-77.)

B. Cardiovascular Tests (Effective For Services Performed On or After January 1, 1997).--
Do not pay for the following phonocardiography and vectorcardiography diagnostic tests because they have been determined to be outmoded and of little clinical value. They include:

- CPT code 93201, Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),
- CPT code 93202, Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic),
- CPT code 93204, Phonocardiogram; interpretation and report,
- CPT code 93205, Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,
- CPT code 93208, Phonocardiogram; without interpretation and report,
- CPT code 93209, Phonocardiogram; interpretation and report only,
- CPT code 93210, Intracardiac,
- CPT code 93220, Vectorcardiogram (VCG), with or without ECG; with interpretation and report,
- CPT code 93221, Vectorcardiogram; tracing only, without interpretation and report, and
- CPT code 93222, Vectorcardiogram; interpretation and report only.

60-3 WHITE CANE FOR USE BY A BLIND PERSON--NOT COVERED *[contents]*

A white cane for use by a blind person is more an identifying and self-help device rather than an item which makes a meaningful contribution in the treatment of an illness or injury.

60-4 HOME USE OF OXYGEN *[contents]*

A. General.--Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6)of the Act) is considered reasonable and

necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.

B. Medical documentation.--Initial claims for oxygen services must include a completed Form HCFA-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form HCFA-484 for recertifications. (See Medicare Carriers Manual §3312 for completion of
Form HCFA-484.)

The medical and prescription information in section B of Form HCFA-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by nonphysician clinician or a physician employee, it must be reviewed and the form HCFA-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. (See Medicare Carriers Manual, Part 3,§4105.5.) This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- A diagnosis of the disease requiring home use of oxygen;

- The oxygen flow rate; and

- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the carrier's medical staff should review all claims with oxygen flow rates of more than 4 liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed form HCFA-484. In addition the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the noncontinuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the carrier in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

Carriers are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in Medicare Carriers Manual, Part 3, §4105.5. When indicated, carriers may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See Medicare Carriers Manual §4105.5 for certification and retesting schedules.)

C. Laboratory Evidence.--Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO_2) in arterial blood. (See Medicare Carriers Manual, Part 3, §2070.1 for instructions on clinical laboratory tests.) A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending physician and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines. This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the carrier needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than 2 days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease."

Carriers may accept an attending physician's statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the carrier has reason to believe that there has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D. Health Conditions.--Coverage is available for patients with significant hypoxemia in the chronic stable state if: (1) the attending physician has determined that the patient has a health condition outlined in subsection D.1, (2) the patient meets the blood gas evidence requirements specified in subsection D.3, and (3) the patient has appropriately tried other alternative treatment measures without complete success. (See subsection B.)

1. Conditions for Which Oxygen Therapy May Be Covered.--

o A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, whether of known or unknown etiology; cystic fibrosis bronchiectasis; widespread pulmonary neoplasm; or

o Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. Conditions for Which Oxygen Therapy Is Not Covered.--

o Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;

o Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;

o Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO_2 improves the oxygenation of tissues with impaired circulation; or

o Terminal illnesses that do not affect the lungs.

3. Covered Blood Gas Values.--If the patient has a condition specified in subsection D.1, the carrier must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

a. Group I.--Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by any of the following:

(1) An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken at rest, breathing room air.

(2) An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO_2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.

(3) An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

b. Group II.--Except as modified in subsection d, coverage is available for patients whose arterial PO_2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent, if there is evidence of:

(1) Dependent edema suggesting congestive heart failure;

(2) Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVFL; or

(3) Erythrocythemia with a hematocrit greater than 56 percent.

c. Group III.--Except as modified in subsection d, carriers must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO_2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent. In order for claims in this category to be reimbursed, the carrier's reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims. HCFA expects few claims to be approved for coverage in this category.

d. Variable Factors That May Affect Blood Gas Values.--In reviewing the arterial PO_2 levels and the arterial oxygen saturation percentages specified in subsections D. 3. a, b and c, the carrier's medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

E. Portable Oxygen Systems.--A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

o The claim meets the requirements specified in subsections A-D, as appropriate; and

o The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep.

F. Respiratory Therapists.--Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B durable medical equipment benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §60-9; Intermediary Manual, Part 3, §3113ff; and Medicare Carriers Manual, Part 3, §2100ff.)

60-5 POWER-OPERATED VEHICLES THAT MAY BE USED AS WHEELCHAIRS

[contents]

Power-operated vehicles that may be appropriately used as wheelchairs are covered under the durable medical equipment provision.

These vehicles have been appropriately used in the home setting for vocational rehabilitation and to improve the ability of chronically disabled persons to cope with normal domestic, vocational and social activities. They may be covered if a wheelchair is medically necessary and the patient is unable to operate a wheelchair manually.

A specialist in physical medicine, orthopedic surgery, neurology, or rheumatology must provide an evaluation of the patient's medical and physical condition and a prescription for the vehicle to assure that the patient requires the vehicle and is capable of using it safely. When an intermediary determines that such a specialist is not reasonably accessible, e.g., more than 1 day's round trip from the beneficiary's home, or the patient's condition precludes such travel, a prescription from the beneficiary's physician is acceptable.

The intermediary's medical staff reviews all claims for a power-operated vehicle, including the specialists' or other physicians' prescriptions and evaluations of the patient's medical and physical conditions, to insure that all coverage requirements are met. (See §60-9 and Intermediary Manual, Part 3, §3629.)

60-6 SPECIALLY SIZED WHEELCHAIRS *[contents]*

Payment may be made for a specially sized wheelchair even though it is more expensive than a standard wheelchair. For example, a narrow wheelchair may be required because of the narrow doorways of a patient's home or because of a patient's slender build. Such difference in the size of the wheelchair from the standard model is not considered a deluxe feature.

A physician's certification or prescription that a special size is needed is not required where you can determine from the information in file or other sources that a specially sized wheelchair (rather than a standard one) is needed to accommodate the wheelchair to the place of use or the physical size of the patient.

To determine the reasonable charge in these cases, use the criteria set out in Medicare Carriers Manual, §§5022, 5022.1, 5200, and 5205, as necessary *(Note: Sections 5022, 5022.1, and 5205 are not present in the current version of the Medicare Carriers Manual)*.

Cross-refer: Intermediary Manual, §§3113.2C, 3642.1, and 3643 (item 3) *(Note: Sections 3642.1 and 3643 (item 3) are not present in the current version of the Intermediary Manual)*; Medicare Carriers Manual, §§2100.2c, 2105, 4105.2, and 5107 *(Note: Section 4105.2 is not present in the current version of the Medicare Carriers Manual)*; Hospital Manual, §§235.2c, 420.1 (item 13) *(Note: Section 420.1 is not present in the current version of the Hospital Manual)*.

60-8 SEAT LIFT [contents]

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.

Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position. Limit the payment for units which incorporate a recliner feature along with the seat lift to the amount payable for a seat lift without this feature.

Cross Refer: Medicare Carriers Manual, § 5107 *(Note: Section 5107 is not present in the current version of the Medicare Carriers Manual).*

60-9 DURABLE MEDICAL EQUIPMENT REFERENCE LIST. [contents]

The durable medical equipment (DME) list which follows is designed to facilitate your processing of DME claims. This section is designed to be used as a quick reference tool for determining the coverage status of certain pieces of DME and especially for those items which are commonly referred to by both brand and generic names. The information contained herein is applicable (where appropriate) to all DME coverage determinations discussed in the DME portion of this manual. The list is organized into two columns. The first column lists alphabetically various generic categories of equipment on which national coverage decisions have been made by HCFA; and the second column notes the coverage status of each equipment category.

In the case of equipment categories that have been determined by HCFA to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. This DME list will be updated periodically to reflect any additional national coverage decisions that HCFA may make with regard to other categories of equipment.

When you receive a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed, you have the authority and responsibility for deciding whether those items are covered under the DME benefit. These decisions must be made by each contractor based on the advice of its medical consultants, taking into account:

- The general DME coverage instructions in the Medicare Carriers Manual, §2100ff and Intermediary Manual, §3113ff (see below for brief summary);

- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) (see Medicare Carriers Manual, §2303.1 and Intermediary Manual, §3151.1) and is otherwise generally considered to be safe and effective for the purpose intended; and

- Whether the item is reasonable and necessary for the individual patient.

As provided in the Medicare Carriers Manual, § 2100.1, and Intermediary Manual, §3113.1, the term DME is defined as equipment which

- Can withstand repeated use; i.e., could normally be rented, and used by successive patients;

- Is primarily and customarily used to serve a medical purpose;

- Generally is not useful to a person in the absence of illness or injury; and

- Is appropriate for use in a patient's home.

Durable Medical Equipment Reference List:

Item	Coverage Status
Air Cleaners	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act)
Air Conditioners	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act)
Air-Fluidized Bed	(See §60-19.)
Alternating Pressure Pads, and Mattresses and Lambs Wool Pads	Covered if patient has, or is highly susceptible to, decubitus ulcers and patient's physician has specified that he will be supervising its use in connection with his course of treatment.
Audible/Visible Signal Pacemaker Monitor	(See Self-Contained Pacemaker Monitor.)

Augmentative Communication Device	(See Speech Generating Devices, §60-23.)
Bathtub Lifts	Deny--convenience item; not primarily medical in nature (§l861(n) of the Act)
Bathtub Seats	Deny--comfort or convenience item; hygienic equipment; not primarily medical in nature (§l861(n) of the Act)
Bead Bed	(See §60-19.)
Bed Baths (home type)	Deny--hygienic equipment; not primarily medical in nature (§l861(n) of the Act)
Bed Lifter (bed elevator)	Deny--not primarily medical in nature (§1861(n) of the Act.
Bed boards	Deny--not primarily medical in nature (§1861(n) of the Act)
Bed Pans (autoclavable hospital type)	Covered if patient is bed confined
Bed Side Rails	(See Hospital Beds, §60-l8.)
Beds-Lounge (power or manual)	Deny--not a hospital bed; comfort or convenience item; not primarily medical in nature (§l86l(n) of the Act)
Beds--Oscillating	Deny--institutional equipment; inappropriate for home use
Bidet Toilet Seat	(See Toilet Seats.)
Blood Glucose Analyzer Reflectance Colorimeter	Deny--unsuitable for home use (See §60-11.)
Blood Glucose Monitor	Covered if patient meets certain conditions (See §60-11.)
Braille Teaching Texts	Deny--educational equipment; not primarily medical in nature (§1861(n) of the Act)
Canes	Covered if patient's condition impairs ambulation (See §60-3.)
Carafes	Deny--convenience item; not primarily medical in nature (§l861(n) of the Act)
Catheters	Deny--nonreusable disposable supply (§l861(n) of the Act)
Commodes	Covered if patient is confined to bed or room.

	NOTE: The term "room confined" means that the patient's condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally would not be a factor in this determination. However, confinement of a patient to his home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient's medical condition confines him to a floor of his home and there is no bathroom located on that floor (See hospital beds in §60-18 for definition of "bed confinement".)
Communicator	(See §60-23, Speech Generating Devices)
Continuous Passive Motion	Continuous passive motion devices are devices covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the three-week period following surgery during which the device is used in the patient's home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.
Continuous Positive Airway Pressure (CPAP)	(See §60-17.)
Crutches	Covered if patient's condition impairs Ambulation
Cushion Lift Power Seat	(See Seat Lifts.)
Dehumidifiers (room or central heating system type)	Deny--environmental control equipment; not primarily medical in nature (§l861(n) of the Act
Diathermy Machines (standard pulses wave types)	Deny--inappropriate for home use (See and §35-41.)
Digital Electronic Pacemaker Monitor	(See Self-Contained Pacemaker Monitor.)</TD< tr>
Disposable Sheets and Bags	Deny--nonreusable disposable supplies (§l861(n) of the Act)
Elastic Stockings	Deny--nonreusable supply; not rental-type items (§l861(n) of the Act)
Electric Air Cleaners	Deny--(See Air Cleaners.) (§l861(n) of the Act)

Electric Hospital Beds	(See Hospital Beds §60-18.)
Electrostatic Machines	Deny--(See Air Cleaners and Air Conditioners.) (§1861(n) of the Act)
Elevators	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Emesis Basins	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Esophageal Dilator	Deny--physician instrument; inappropriate for patient use
Exercise Equipment	Deny--not primarily medical in nature (§1861(n) of the Act)
Fabric Supports	Deny--nonreusable supplies; not rental-type it (§1861(n) of the Act)
Face Masks (oxygen)	Covered if oxygen is covered (See § 60-4.)
Face Masks (surgical)	Deny--nonreusable disposable items (§1861(n) of the Act)
Flowmeter	(See Medical Oxygen Regulators)
Fluidic Breathing Assister	(See IPPB Machines.)
Fomentation Device	(See Heating Pads.)
Gel Flotation Pads and Mattresses	(See Alternating Pressure Pads and Mattresses.)
Grab Bars	Deny--self-help device; not primarily medical in nature (§1861(n) of the Act)
Heat and Massage Foam Cushion Pad	Deny--not primarily medical in nature; personal comfort item (§§ 1861(n) and 1862(a)(6) of the Act)
Heating and Cooling Plants	Deny--environmental control equipment; not primarily medical in nature(§1861(n) of the Act)
Heating Pads	Covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective.
Heat Lamps	Covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective.
Hospital Beds	(See § 60-18.)

Hot Packs	(See Heating Pads.)
Humidifiers (oxygen)	(See Oxygen Humidifiers.)
Humidifiers (room or central heating system types)	Deny--environmental control equipment; not medical in nature (§l861(n) of the Act)
Hydraulic Lift	(See Patient Lifts.)
Incontinent Pads	Deny--nonreusable supply; hygienic item (§ l861(n) of the Act.)
Infusion Pumps	For external and implantable pumps, see §60-14. If the pump is used with an enteral or parenteral ralnutritional therapy system, see §§65-10 - 65.10.2 0.2 for special coverage rules.
Injectors (hypodermic jet devices for injection of insulin	Deny-- noncovered self-administered drug supply, (§ 1861(s)(2)(A) of the Act)
IPPB Machines	Covered if patient's ability to breathe is severely impaired
Iron Lungs	(See Ventilators.)
Irrigating Kit	Deny--nonreusable supply; hygienic equipment (§l861(n) of the Act)
Lambs Wool Pads	Covered under same conditions as alternating pressure pads and mattresses
Leotards	Deny--(See Pressure Leotards.) (§l861(n)of the Act)
Lymphedema Pumps	Covered (See §60-16.)(segmental and non-segmental therapy types)
Massage Devices	Deny--personal comfort items; not primarily medical in nature (§§l861(n) and l862(a)(6) of the Act)
Mattress	Covered only where hospital bed is medically necessary (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See §60-18.)
Medical Oxygen Regulators	Covered if patient's ability to breathe is severely impaired (See §60-4.)
Mobile Geriatric Chair	(See Rolling Chairs.)
Motorized Wheelchairs	(See Wheelchairs (power operated).)
Muscle Stimulators	Covered for certain conditions (See §35-77.)
Nebulizers	Covered if patient's ability to breathe is severely impaired
Oscillating Beds	Deny--institutional equipment--inappropriate for home use

Over bed Tables	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Oxygen	Covered if the oxygen has been prescribed for use in connection with medically necessary durable medical equipment (See §60-4.)
Oxygen Humidifiers	Covered if a medical humidifier has been prescribed for use in connection with medically necessary durable medical equipment for purposes of moisturizing oxygen (See §60-4.)
Oxygen Regulators (Medical)	(See Medical Oxygen Regulators.)
Oxygen Tents	(See § 60-4.)
Paraffin Bath Units (Portable)	(See Portable Paraffin Bath Units.)
Paraffin Bath Units (Standard)	Deny--institutional equipment; inappropriate for home use
Parallel Bars	Deny--support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., a walker) satisfy the patient's need
Patient Lifts	Covered if contractor's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest or retard deterioration in his condition.
Percussors	Covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient or operator of powered percussor has received appropriate training by a physician or therapist, and no one competent to administer manual therapy is available.
Portable Oxygen Systems:	1. Regulated (adjustable --covered under conditions specified in flow rate) §60-4. Refer all claims to medical staff for this determination. 2. Preset (flow rate --deny--emergency, first-aid, or not adjustable) precautionary equipment; essentially not therapeutic in nature
Portable Paraffin Bath Units	Covered when the patient has undergone a successful trial period of paraffin therapy ordered by a physician and the patient's condition is expected to be relieved by long-term use of this modality.
Portable Room Heaters	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act)
Portable Whirlpool Pumps	Deny--not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act)
Postural Drainage Boards	Covered if patient has a chronic pulmonary condition

Preset Portable Oxygen Units	Deny--emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature
Pressure Leotards	Deny--nonreusable supply, not rental-type item (§1861(n) of the Act)
Pulse Tachometer	Deny--not reasonable or necessary for monitoring pulse of homebound patient with or without a cardiac pacemaker
Quad-Canes	(See Walkers.)
Raised Toilet Seats	Deny--convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act)
Reflectance Colorimeters	(See Blood Glucose Analyzers.)
Respirators	(See Ventilators.)
Rolling Chairs	Covered if the contractor's medical staff determines that the patient's condition is such that there is a medical need for this item and it has been prescribed by the patient's physician in lieu of a wheelchair. Coverage is limited to those rollabout chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals. Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care or treatment of ill or injured persons. This type is not primarily medical in nature. (§1861(n) of the Act)
Safety Roller	(See §60-15.)
Sauna Baths	Deny--not primarily medical in nature; personal comfort items (§§1861(n) and (1862(a)(6) of the Act)
Seat Lift	Covered under the conditions specified in §60-8. Refer all to medical staff for this determination.
Self-Contained Pacemaker Monitor	Covered when prescribed by a physician for a patient with a cardiac pacemaker (See §§50-1C and 60-7.)
Sitz Bath	Covered if the contractor's medical staff determines patient has an infection or injury of the perineal area and the item has been prescribed by the patient's physician as a part of his planned regimen of treatment in the patient's home.
Spare Tanks of Oxygen	Deny--convenience or precautionary supply
Speech Teaching	Deny--education equipment; not primarily medical in nature (§1861(n) of

Machine	the Act)
Stairway Elevators	Deny--(See Elevators.) (§l861(n) of the Act)
Standing Table	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Steam Packs	These packs are covered under the same condition as a heating pad (See Heating Pads.)
Suction Machine	Covered if the contractor's medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical or professional supervision.
Support Hose	Deny (See Fabric Supports.) (§l861(n) of the Act)
Surgical Leggings	Deny--nonreusable supply; not rental-type item (§l861(n) of the Act)
Telephone Alert Systems	Deny--these are emergency communications systems and do not serve a diagnostic or therapeutic purpose
Telephone Arms	Deny--convenience item; not medical in nature (§l861(n) of the Act)
Toilet Seats	Deny--not medical equipment (§l861(n)of the Act)
Traction Equipment	Covered if patient has orthopedic impairment requiring traction equipment which prevents ambulation during the period of use (Consider covering devices usable during ambulation; e.g., cervical traction collar, under the brace provision)
Trapeze Bars	Covered if patient is bed confined and the patient needs a trapeze bar to sit up because of respiratory condition, to change body position for other medical reasons, or to get in and out of bed.
Treadmill Exerciser	Deny--exercise equipment; not primarily medical in nature(§l861(n) of the Act)
Ultraviolet Cabinet	Covered for selected patients with generalized intractable psoriasis. Using appropriate consultation, the contractor should determine whether medical and other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.
Urinals (autoclavable hospital type)	Covered if patient is bed confined
Vaporizers	Covered if patient has a respiratory illness

Ventilators	Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive and negative pressure types.
Walkers	Covered if patient's condition impairs ambulation (See also §60-15.)
Water and Pressure Pads and Mattresses	(See Alternating Pressure Pads and Mattresses.)
Wheelchairs	Covered if patient's condition is such that without the use of a wheelchair he would otherwise be bed or chair confined. An individual may qualify for a wheelchair and still be considered bed confined.
Wheelchairs (power operated) and wheelchairs with other special features	Covered if patient's condition is such and that a wheelchair is medically necessary and the patient is unable to operate the wheelchair manually. Any claim involving a power wheelchair or a wheelchair with other special features should be referred for medical consultation since payment for the special features is limited to those which are medically required because of the patient's condition. (See §60-5 for power operated and §60-6 for specially sized wheelchairs.) NOTE: A power-operated vehicle that may appropriately be used as a wheelchair can be covered. (See §60-5 for coverage details.)
Whirlpool Bath Equipment	Covered if patient is homebound and has a (standard) condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere; e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for a determination.
Whirlpool Pumps	Deny--(See Portable Whirlpool Pumps.) (§1861(n) of the Act)
White Cane	Deny-- (See §60-3.)

60-15 SAFETY ROLLER (Effective for Claims Adjudicated On or After 6/3/85)

[contents]

"Safety roller" is the generic name applied to devices for patients who cannot use standard wheeled walkers. They may be appropriate, and therefore covered, for some patients who are obese, have severe neurological disorders, or restricted use of one hand, which makes it impossible to use a wheeled walker that does not have the sophisticated braking system found on safety rollers.

In order to assure that payment is not made for a safety roller when a less expensive standard wheeled walker would satisfy the patient's medical needs, carriers refer safety roller claims to their medical consultants. The medical consultant determines whether some or all of the features provided in a safety roller are necessary, and therefore covered and reimbursable. If it is determined that the patient could use a standard wheeled walker, the charge for the safety roller is reduced to the charge of a standard wheeled walker.

Some obese patients who could use a standard wheeled walker if their weight did not exceed the walker's strength and stability limits can have it reinforced and its wheelbase expanded. Such modifications are routine mechanical adjustments and justify a moderate surcharge. In these cases the carrier reduces the charge for the safety roller to the charge for the standard wheeled walker plus the surcharge for modifications.

In the case of patients with medical documentation showing severe neurological disorders or restricted use of one hand which makes it impossible for them to use a wheeled walker that does not have a sophisticated braking system, a reasonable charge for the safety roller may be determined without relating it to the reasonable charge for a standard wheeled walker. (Such reasonable charge should be developed in accordance with the instructions in Medicare Carriers Manual §§5010 and 5205.)

Cross Refer: Medicare Carriers Manual §§2100ff., §60-9.

60-16. PNEUMATIC COMPRESSION DEVICES (USED FOR LYMPHEDEMA)

[contents]

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from an impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. It is a relatively uncommon, chronic condition which may be due to many causes, e.g., surgical removal of lymph nodes, post radiation fibrosis, scarring of lymphatic channel, onset of puberty (Milroy's Disease), and congenital anomalies. In the home setting, both the segmental and nonsegmented pneumatic compression devices are covered only for the treatment of generalized, refractory lymphedema.

Pneumatic compression devices are only covered as a treatment of last resort, i.e., other less intensive treatments must have been tried first and found inadequate. Such treatments would include leg or arm elevation and custom fabricated gradient pressure stockings or sleeves. Pneumatic compression devices may be covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include (1) the patient's diagnosis and prognosis; (2) symptoms and objective findings, including measurements which establish the severity of the condition; (3) the reason the device is required, including the treatments which have been tried and failed; and (4) the clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

In general, the nonsegmented (HCPCS code E0650) or segmented (HCPCS code E0651) compression device without manual control of pressure in each chamber is considered the least costly alternative that meets the clinical needs of the individual. Therefore, when a claim for a segmented pneumatic compression device which allows for manual control in each chamber is received, payment must be made for the least expensive medically appropriate device. If the patient medically needs a segmented device but does not need manual controls, payment must be made for HCPCS code E0651. The segmented device with manual control (HCPCS code E0652) is covered only when there are unique characteristics that prevent the individual from receiving satisfactory pneumatic treatment using a less costly device, e.g., significant sensitive skin scars or the presence of contracture or pain caused by a clinical condition that requires the more costly manual control device.

The use of pneumatic compression devices may be medically appropriate only for those patients with generalized, refractory edema from venous insufficiency with lymphatic obstruction (i.e., recurrent cellulitis with secondary scarring of the lymphatic system) with significant ulceration of the lower extremity(ies) who have received repeated, standard treatment from a physician using such methods as a compression bandage system or its equivalent, but fail to heal after 6 months of continuous treatment. The exact nature of the medical problem must be clear from the medical evidence submitted. If, after obtaining this information, a question of medical necessity remains, the contractor's medical staff resolves the issue.

Cross Refer: §60-9.

60-18. HOSPITAL BEDS *[contents]*

A. General Requirements for Coverage of Hospital Beds.--A physician's prescription, and such additional documentation as the contractors' medical staffs may consider necessary, including medical records and physicians' reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

o The patient's condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or

- The patient's condition requires special attachments that cannot be fixed and used on an ordinary bed.

B. Physician's Prescription.--The physician's prescription, which must accompany the initial claim, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the patient's condition requires positioning, the prescription or other documentation must describe the medical condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition, that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient's condition requires special attachments, the prescription must describe the patient's condition and specify the attachments that require a hospital bed.

C. Variable Height Feature.--In well documented cases, the contractors' medical staffs may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:
   - Severe arthritis and other injuries to lower extremities; e.g., fractured hip. The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;
   - Severe cardiac conditions. For those cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down;
   - Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair, with or without help; or
   - Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.

D. Electric Powered Hospital Bed Adjustments.--Electric powered adjustments to lower and raise head and foot may be covered when the contractor's medical staff determines that the patient's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the patient can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and brain damaged patients.

E. Side Rails.--If the patient's condition requires bed side rails, they can be covered when an integral part of, or an accessory to, a hospital bed.

Cross refer: Medicare Carriers Manual, §5015.4

60-19. AIR-FLUIDIZED BED (Effective for services rendered on or after: 07/30/90)

[contents]

An air-fluidized bed uses warm air under pressure to set small ceramic beads in motion which simulate the movement of fluid. When the patient is placed in the bed, his body weight is evenly distributed over a large surface area which creates a sensation of "floating." Medicare payment for home use of the air-fluidized bed for treatment of pressure sores can be made if such use is reasonable and necessary for the individual patient.

A decision that use of an air-fluidized bed is reasonable and necessary requires that:

- The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore;

- The patient is bedridden or chair bound as a result of severely limited mobility;
- In the absence of an air-fluidized bed, the patient would require institutionalization;
- The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. This course of treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment has been rendered.
- Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days, will not preclude coverage of air-fluidized bed. Should additional debridement again become necessary, while a patient is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to become non-covered. In all instances documentation verifying the continued need for the bed must be available.
- Conservative treatment must include:

  - Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours);

  - Use of a specialized support surface (Group II) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation;

  - Necessary treatment to resolve any wound infection;

  - Optimization of nutrition status to promote wound healing;

  - Debridement by any means (including wet to dry dressings-which does not require an occulsive covering) to remove devitalized tissue from the wound bed;

- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

- A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage;
- A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis; and
- All other alternative equipment has been considered and ruled out.

Home use of the air-fluidized bed is not covered under any of the following circumstances:

- The patient has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);

- The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material; an air-fluidized bed;
- The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed;
- Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);
- Electrical system is insufficient for the anticipated increase in energy consumption; or
- Other known contraindications exist.

Coverage of an air-fluidized bed is limited to the equipment itself. Payment for this covered item may only be made if the written order from the attending physician is furnished to the supplier prior to the delivery of the equipment. Payment is not included for the caregiver or for architectural adjustments such as electrical or structural improvement.
Cross refer: Medicare Carriers Manual, §5102.2.

60-20 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS (TENS)

[contents]

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. (See §45-25 for an explanation of coverage of medically necessary supplies for the effective use of TENS and §45-19 for an explanation of coverage of TENS for acute post-operative pain.)

60-21 INTRAPULMONARY PERCUSSIVE VENTILATOR (IPV) - NOT COVERED

[contents]

IPV is a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient's chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.

Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting. There are no data to support the effectiveness of the device. Therefore, IPV in the home setting is not covered.

60-23 SPEECH GENERATING DEVICES

[contents]

Effective January 1, 2001, augmentative and alternative communication devices or communicators, which are hereafter referred to as "speech generating devices" are now considered to fall within the DME benefit category established by §1861(n) of the Social Security Act. They may be covered if the contractor's medical staff determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device based on the following definitions.

Definition of Speech Generating Devices

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating are characterized by:

- Being a dedicated speech device, used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time;
- May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access; or
- May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech-generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of §1861(n) are characterized by:

- Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical functions.
- Laptop computers, desktop computers, or PDAs, which may be programmed to perform the same function as a speech generating device, are non-covered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech-generating devices for Medicare coverage purposes.
- A device that is useful to someone without severe speech impairment is not considered a speech-generating device for Medicare coverage purposes.

60-24 NON-IMPLANTABLE PELVIC FLOOR ELECTRICAL STIMULATOR

[contents]

Non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis.

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

65-2 ELECTRICAL CONTINENCE AID--NOT COVERED

[contents]

An electrical continence aid is a device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety. Therefore, they are not covered under

Medicare since they cannot be considered to be reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by §1862(a)(1) of the law.

65-5 ELECTRONIC SPEECH AIDS *[contents]*

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-refer: HCFA-Pub. 13-3, §3110.4; HCFA-Pub. 14-3, §2130; HCFA-Pub. 10, §228.4

65-8 ELECTRICAL NERVE STIMULATORS *[contents]*

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators.--Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in §35-46, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators).--The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations.--There are two types of implantations covered by this instruction:

a. Dorsal Column (Spinal Cord) Neurostimulation.--The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.

b. Depth Brain Neurostimulation.--The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage.--No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:

a. The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;

b. With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;

c. Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);

d. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy item c) must be available; and

e. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Contractors may find it helpful to work with PROs to obtain the information needed to apply these conditions to claims.

See Intermediary Manual, §3110.4 and §§35-20 and 35-27.

65-9 INCONTINENCE CONTROL DEVICES *[contents]*

A. Mechanical/Hydraulic Incontinence Control Devices.--Mechanical/hydraulic incontinence control devices are accepted as safe and effective in the management of urinary incontinence in patients with permanent anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device. Such a device is covered when its use is reasonable and necessary for the individual patient.

B. Collagen Implant.--A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4-week period.

In male patients, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The patient then is asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the patient leaks, the diagnosis of ISD is established.

In female patients, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H2O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) when the bladder has been filled with a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H2O, the diagnosis of ISD is established.

To use a collagen implant, physicians must have urology training in the use of a cystoscope and must complete a collagen implant training program.

Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;

- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;

- Male patients following trauma, including prostatectomy and/or radiation; and

- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H2O or less.

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may

benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

See Intermediary Manual, §3110.4.

C. Non-Implantable Pelvic Floor Electrical Stimulator.--(See §60-24.)

70-3 PROSTHETIC SHOE *[contents]*

A prosthetic shoe (a device used when all or a substantial portion of the front part of the foot is missing) can be covered as a terminal device; i.e., a structural supplement replacing a totally or substantially absent hand or foot. The coverage of artificial arms and legs includes payment for terminal devices such as hands or hooks even though the patient may not require an artificial limb. The function of the prosthetic shoe is quite distinct from that of excluded orthopedic shoe and supportive foot devices which are used by individuals whose feet, although impaired, are essentially intact. (Section l862(a)(8) of the Act excludes payment for orthopedic shoes or other supportive devices for the feet.)

See Intermediary Manual, §3110.5; Medicare Carriers Manual, §2133; and Hospital Manual, §228.5.

80-1 INSTITUTIONAL AND HOME CARE PATIENT EDUCATION PROGRAMS *[contents]*

While the Act does not specifically identify patient education programs as covered services, reimbursement may be made under Medicare for such programs furnished by providers of services (i.e., hospitals, SNFs, HHAs, and OPT providers) to the extent that the programs are appropriate, integral parts in the rendition of covered services which are reasonable and necessary for the treatment of the individual's illness or injury. For example, educational activities carried out by nurses such as teaching patients to give themselves injections, follow prescribed diets, administer colostomy care, administer medical gases, and carry out other inpatient care activities may be reimbursable as a part of covered routine nursing care. Also, the teaching by an occupational therapist of compensatory techniques to improve a patient's level of independence in the activities of daily living may be reimbursed as a part of covered occupational therapy. Similarly, the instruction of a patient in the carrying out of a maintenance program designed for him/her by a physical therapist may be reimbursed as part of covered physical therapy.

However, when the educational activities are not closely related to the care and treatment of the patient, such as programs directed toward instructing patients or the public generally in

preventive health care activities, reimbursement cannot be made since the Act limits Medicare payment to covered care which is reasonable and necessary for the treatment of an illness or injury. For example, programs designed to prevent illness by instructing the general public in the importance of good nutritional habits, exercise regimens, and good hygiene are not reimbursable under Medicare.